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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,703	11/12/2003	Marlies Regiert	REGIERT ET AL-2	9249

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EXAMINER	
ISSAC, ROY P	

ART UNIT	PAPER NUMBER
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/712,703	REGIERT ET AL.	
	Examiner	Art Unit	
	Roy P. Issac	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to Applicant's amendment/ remarks/ response filed 7/12/2007, wherein claims 4-8 and 10-18 have been cancelled and claims 1 and 9 have been amended. Claims 1 and 9 are currently pending and are examined on the merits herein.

Rejections Withdrawn

In view of the cancellation of claims 4-8 and 10-18, all rejections made with respect to claims 4-8 and 10-18 in the previous office action are withdrawn.

Applicant's amendment deleting complexes of beta and gamma cyclodextrin and 1:1 and 1:2 complexes of alpha cylodextrin overcomes the rejections of claim 1 under section 102(b) over Lopez-Nicolas et. al.

Applicant's amendment deleting complexes of beta and gamma cyclodextrin and 1:1 and 1:2 complexes of alpha cylodextrin overcomes the rejections of claim 1 under section 102(b) over Lajos Szente et. al.

Applicant's amendment deleting complexes of beta and gamma cyclodextrin and 1:1 and 1:2 complexes of alpha cylodextrin overcomes the rejections of claims 1 and 9 under section 103 over Wimmer in view of Lopez-Nicolas further in view of Koulbanis.

The following is a new ground of rejection necessitated by applicants' amendments:

Claims 1 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bruzzese et. al. (EP 0470452; Of record) in view of Schlenk et. al. (J. Am. Chem. Soc., 83, 2312-2320; 1961; Of record) further in view of Koulbanis et. al. (U.S. Patent No. 4,393,043; Of Record).

Bruzzese et. al. discloses a method for the production of complexes of long chain polyunsaturated fatty acid with cyclodextrin. (Abstract; Column 3, paragraph 2). Bruzzese et. al. discloses a series of complexes of eicosapentaenoic acid and docosahexaenoic acid, both essential fatty acids, in 1:1, 1:1.25, 1:2 and 1:3 ratios. (Examples 1, 4, 5, 6, 7, 8, 9 and 10; Columns 4-7). Bruzzese further discloses complexes of α-cyclodextrin with essential fatty acids. (Example 6). The GC analysis of the product made shows an oil content of 26.3% representing a molar ratio of about 1:1 with cyclodextrin. However, there is no indication as to whether complexes of 3:1 or 4:1 ratios were present in the product mixture. Note that it is considered well within the basic skills of one of ordinary skill in the art to change the amount of ingredients during the preparation of guest-host complexes to prepare complexes of higher order.

Bruzzese et. al. does not expressly disclose a 3:1 or 4:1 complex of alpha cyclodextrin with an essential fatty acid or an emulsion made with said complex.

Schlenk et. al. discloses that fatty acids with 17 and higher carbons produce 1:3 complexes with cyclodextrins. (Page 2317, Column 2, paragraph 3, lines 10-20; Page 2315, Column 1, Figure 4). The figure indicate a relation between fatty acid chain length and the number of cyclodextrins in the complex. (Figure 4, right axis). The figure

indicate a preference for alpha cyclodextrin to form higher order complexes. Schlenk et. al. indicates that the presence of cyclodextrins increase the solubility of fatty acids. (Page 2317, Column1, Paragraph 2). Note that most essential fatty acids are of chain lengths 15 and higher.

Koulbanis et. al. discloses the use of vitamin F for the preparation of cosmetics. (Column 1, Paragraph 1). Koulbanis et. al. discloses vitamin F as useful for the treatment of skin dryness. (Column 1, lines 27-30). Koulbanis et. al. further disclose that the use of vitamin F is limited by problems with oxidation. (Column 1, lines 30-35). Koulbanis further discloses several emulsions comprising vitamin F compounds and oil by mixing the ingredients. (Columns 5-6; Examples II-XII). Note that the preparation of a dispersion before the formation of an emulsion is considered a routine step within the capabilities of one skill in the art in the cosmetic art.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare complexes of essential fatty acids with cyclodextrins in the 3:1 or higher ratio and to prepare emulsions with them because Burzzese disclose complexes of essential fatty acids with alpha, beta and gamma cyclodextrins and Schlenk et. al. disclose a chain length to complexation ratio in which alpha cyclodextrins forms higher order complexes, and Koulbanis discloses the use of vitamin F in emulsions of topical compositions.

One of ordinary skill in the art would have been motivated to use alpha cyclodextrins to form complexes with essential fatty acids because the complexation increases solubility and alpha cyclodextrin forms higher order complexes with longer

chain fatty acids. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Therefore, one of ordinary skill in the art would have reasonably expected that the use of alpha cyclodextrin with one of the long chain essential fatty acid would have formed a complex of cyclodextrin and essential fatty acid in 3:1 or 4:1 ratio.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

The following are new or modified rejections necessitated by Applicant's amendment filed 7/12/2007, wherein the limitations in pending claims 1 and 9 as amended now have been changed and claims. The limitations in the amended claims have been changed and the breadth and scope of those claims have been changed. Therefore, rejections from the previous Office Action, mailed 2/23/2007, have been modified and are listed below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Bruzzese et. al. (EP 0470452; Of record).

Bruzzese et. al. discloses a method for the production of complexes of long chain polyunsaturated fatty acid with cyclodextrin. (Abstract; Column 3, paragraph 2). Bruzzese et. al. discloses a series of complexes of eicosapentaenoic acid and docosahexaenoic acid, both essential fatty acids, in 1:1, 1:1.25, 1:2 and 1:3 ratios. (Examples 1, 4, 5, 6, 7, 8, 9 and 10; Columns 4-7). Bruzzese further discloses complexes of α-cyclodextrin with essential fatty acids. (Example 6). The GC analysis of the product made shows an oil content of 26.3% representing a molar ratio of about 1:1 with cyclodextrin. However, there is no indication as to whether complexes of 3:1 or 4:1 ratios were present in the product mixture. No analysis of the complex formed that would definitively indicate the individual complexes formed is disclosed. However, one of ordinary skill in the art would find it very likely that a mixture of complexes with 3:1 or 4:1 formed even in small quantities in such product mixtures. Since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald.*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Response to Arguments

Applicant's arguments filed 7/12/2007 have been fully considered but they are not persuasive. Applicants argue that the examiner concedes that there is no Bruzzese does not disclose 3:1 or 4:1 complexes of alpha CD. However, the examiner has only noted that the publication does not expressly disclose a 3:1 or 4:1 comples of alpha CD. As noted above, since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald.*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy P. Issac whose telephone number is 571-272-2674. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

9/19/07

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